

# Balancing Care and Consequences

Ethical Decision-Making for Neonatal Toxicology Testing

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# Disclosures

The presenters do not have any disclosures.

# Introduction- Neonatal Toxicology Testing

- Toxicology testing is a frequently deployed tool by clinicians to identify and manage perinatal substance exposure.
  - Newborns are commonly tested using a variety of samples and a variety of testing techniques\*



Images from: NTL Lab: <https://ntllaboratory.com/Home/Toxicology>, NMS Lab: <https://www.nmslabs.com/solutions/newborn-toxicology/umbilical-cord-collection>

# Introduction- Use of Neonatal Tox Testing

- Neonatal toxicology testing (NTT) may be beneficial in **some** instances
  - Unclear presentation of certain symptoms in a newborn
    - If birthing parent history unobtainable
    - If birthing parent history inconsistent with physical findings, **AFTER** further discussion with the parent to elicit additional information
    - If other etiologies of symptoms have been ruled out
    - If tox testing of the newborn will alter **MEDICAL** management of the newborn

# Introduction- Realities of NTT

- Toxicology testing is not the “gold standard” to identify substance use.
  - Benefits **as well as limitations** are being recognized in the clinical field
- What are we hoping to learn?
- What **can** the test actually tell us?
- What **can't** the test tell us?
  - When? ✗
  - How much? ✗
  - Impact of exposure ✗
  - Who administered the substance? ✗
  - SUD? ✗
  - Safety of newborn discharge? ✗

# Introduction- Realities of NTT

- Variation in practices within and between clinical care sites
  - Lack of clinical guidelines or specific guidance for neonatal toxicology testing “best practices” from major medical organizations
- **Although NTT aims to identify prenatal substance exposure and promote optimal neonatal outcomes, test results may have unintentional negative clinical and social consequences.**

# Why Change Practices in NTT?

- Considerations for practice and policy change include:
  - The birthing parent and the newborn must be considered together in the context of the dyad.
  - Utilize ethical principles
  - Recognize the benefits AND harms of NTT; imperative for clinicians to make better-informed decisions.
  - Acknowledge negative consequences of testing and drive the change needed to minimize consequences and disparities



# Learning Objectives

1. Identify potential harms of neonatal toxicology testing (NTT) and evidence prompting institutions to reconsider their approaches to neonatal toxicology testing
2. List four ethical principles and how they can be applied to NTT
3. Describe the different approaches to NTT and the potential benefits and harms of each
4. Articulate ethics-informed best practices for developing hospital policy for NTT

# Harms of Testing

# Harms of Testing

- False results (both false positives and false negatives)
  - Downstream consequences including inappropriate response to testing
- Child abuse and neglect reports based on a test result when there are no protective/safety concerns
- Harms of testing may outweigh the benefits
- Criteria for testing should optimize medical utility of the test while minimizing potential harms

# Harms of Testing

- Possible **harms** from perinatal toxicology tests include:
  - Disruption of patient-clinician trust
  - Inappropriate treatment plans based upon false positive or false negative results
  - Parent distress and psychological trauma from fear of child welfare involvement
  - Inappropriate test result interpretation
    - Inappropriate child welfare reporting
  - Extended hospitalization to await confirmatory toxicology test results

# Harms- Inequitable Outcomes

- Possible **inequitable outcomes** from perinatal toxicology tests include:
  - Fear of child welfare involvement can lead to disengagement from medical care both prenatally and postnatally\*
    - Worsened health disparities
    - Worsened clinical outcomes
  - Over-reporting of certain patient populations
  - Perpetuation of bias, stigma, racism

# Ethical Principles

# Balancing Benefits and Harms- Ethical Principles

- **Principlism**
  - Respect for autonomy
  - Beneficence
  - Nonmaleficence
  - Justice

# Additional Concepts

- Confidentiality
- Feminist Ethics
- Relational Ethics
- Narrative Ethics
- Trauma-Informed Care
- Paternalism

Ethical Principles and Frameworks	Definitions/Overview	Clinical Application to NTT
Principlism		
Beneficence	Obligation to promote the well-being of the patient <sup>24,25</sup>	<ul style="list-style-type: none"> <li>• Obtaining an NTT to better understand a newborn's clinical presentation or assess for potential exposures with the goal of improving clinical management and outcomes for the newborn</li> </ul>
Nonmaleficence	Duty to avoid or minimize harm to the patient <sup>24,25</sup>	<ul style="list-style-type: none"> <li>• Considering the harms of NTT, including false NTT results, the response to test results, and other downstream consequences</li> </ul>
Justice	Equitable treatment of all patients, as well as equitable distribution of health care resources <sup>24,25</sup>	<ul style="list-style-type: none"> <li>• Avoiding exacerbation/introduction of disparities in NTT and downstream consequences</li> <li>• Considering historical disparities in substance use and SUD, types of substances used, and associated stigma</li> <li>• Providing access to resources to treat SUD and supports for the parent-infant dyad in the outpatient setting</li> </ul>
Autonomy	Recognition of and respect for a patient's right to make informed medical decisions regarding treatment based on their beliefs, opinions, and perspectives, free from controlling inferences from others and personal limitations that prevent meaningful choice <sup>24-26</sup>	<ul style="list-style-type: none"> <li>• Obtaining informed consent (informed parental permission) for NTT</li> <li>• Balancing the obligation to protect and promote the health of the newborn with parental rights (respect for persons)</li> </ul>
Privacy and confidentiality	Clinician responsibility and obligation to respect patient privacy and control or safeguard information gathered about a patient confidentially <sup>24,25,27</sup>	<ul style="list-style-type: none"> <li>• Considering the privacy rights of the parent within the dyad and preserving the confidentiality of information shared in association with their health care</li> </ul>
Feminist ethics	Recognition of historical and ongoing oppression and domination of, and bias against, certain populations (eg, women, children, and people of color), with the goal of addressing power dynamics and social inequities in healthcare <sup>24,28</sup>	<ul style="list-style-type: none"> <li>• Emphasizing equitable decision-making, access to information, and informed consent when ordering NTT</li> </ul>
Relational ethics	Placement of ethical decisions and considerations in the context of relationships and respectful engagement with the goal of establishing a therapeutic alliance and a supportive, accepting environment <sup>26</sup>	<ul style="list-style-type: none"> <li>• Respectfully engaging with, supporting, and accepting parental decisions and life experiences, particularly related to their substance use</li> </ul>
Narrative ethics	Approach to ethical decisions that focuses on understanding personal identity through narratives or stories of a patient or community <sup>29</sup>	<ul style="list-style-type: none"> <li>• Listening to and understanding the unique stories and narratives of the parents of infants with prenatal substance exposure that help inform their values and morals</li> </ul>
Trauma-informed care in ethics	Approach to patient care with sensitivity to possible past trauma and a holistic understanding of the potential stress provoked by new interactions with the health care system <sup>30,31</sup>	<ul style="list-style-type: none"> <li>• Approaching NTT with sensitivity to past trauma experienced by parents, including medical trauma from past health care experiences, which is highly prevalent among those affected by substance use</li> </ul>
Abbreviations: NTT, neonatal toxicology testing; SUD, substance use disorder.		

# Practical Considerations

# Society Guidelines

- ACOG recommends universal screening for substance use at the first prenatal visit via verbal screening to avoid missed cases, discrimination and/or bias based on race/ethnicity or class, and stigma
- Recommendations affirmed by the American Academy of Pediatrics (AAP)
- ACOG and ASAM recommend against routine biochemical testing for illicit substances, partially due to prior work demonstrating racial inequities in which patients undergo these types of testing



American Academy  
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# Screening

- NIDA quick screen

<b>NIDA Quick Screen Question:</b>						
<b><u>In the past year, how often have you used the following?</u></b>	<b>Never</b>	<b>Once or Twice</b>	<b>Monthly</b>	<b>Weekly</b>	<b>Daily or Almost Daily</b>	
<b>Alcohol</b>						
<ul style="list-style-type: none"> <li>• For men, 5 or more drinks a day</li> <li>• For women, 4 or more drinks a day</li> </ul>						
<b>Tobacco Products</b>						
<b>Prescription Drugs for Non-Medical Reasons</b>						
<b>Illegal Drugs</b>						

- 4Ps

- |  |
|--|
| <ul style="list-style-type: none"> <li>• Parents: Did any of your parents have problems with alcohol or other drug use?</li> <li>• Partner: Does your partner have a problem with alcohol or drug use?</li> <li>• Past: In the past, have you had difficulties in your life because of alcohol or other drugs, including prescription medications?</li> <li>• Present: In the past month, have you drunk any alcohol or used other drugs?</li> </ul> |
|--|

# Toxicology testing

How do we decide who to test?

- Universal testing
- Criteria/risk-based testing
- Clinical indications



<https://www.biovantion.com/quality-42612211-rapid-immunoassay-detection-kit-human-immunodeficiency-virus-mtd-opi-oxy-ppx-thc-drug-test>

# Universal testing

- Potential to eliminate bias in testing? Aligns with *justice*?
- Still room for inequity:
  - Interpretation of test results
  - Reporting (Chasnoff 1990, Roberts & Nuru-Jeter 2012)
  - CPS decisions
- Doesn't fix limitations of testing
  - False negatives (Wexelblatt 2015)
  - Prescribed vs. non-prescribed, intrapartum vs. chronic... (Smid 2022)

# Criteria/Risk-based testing

- Clinical utility?

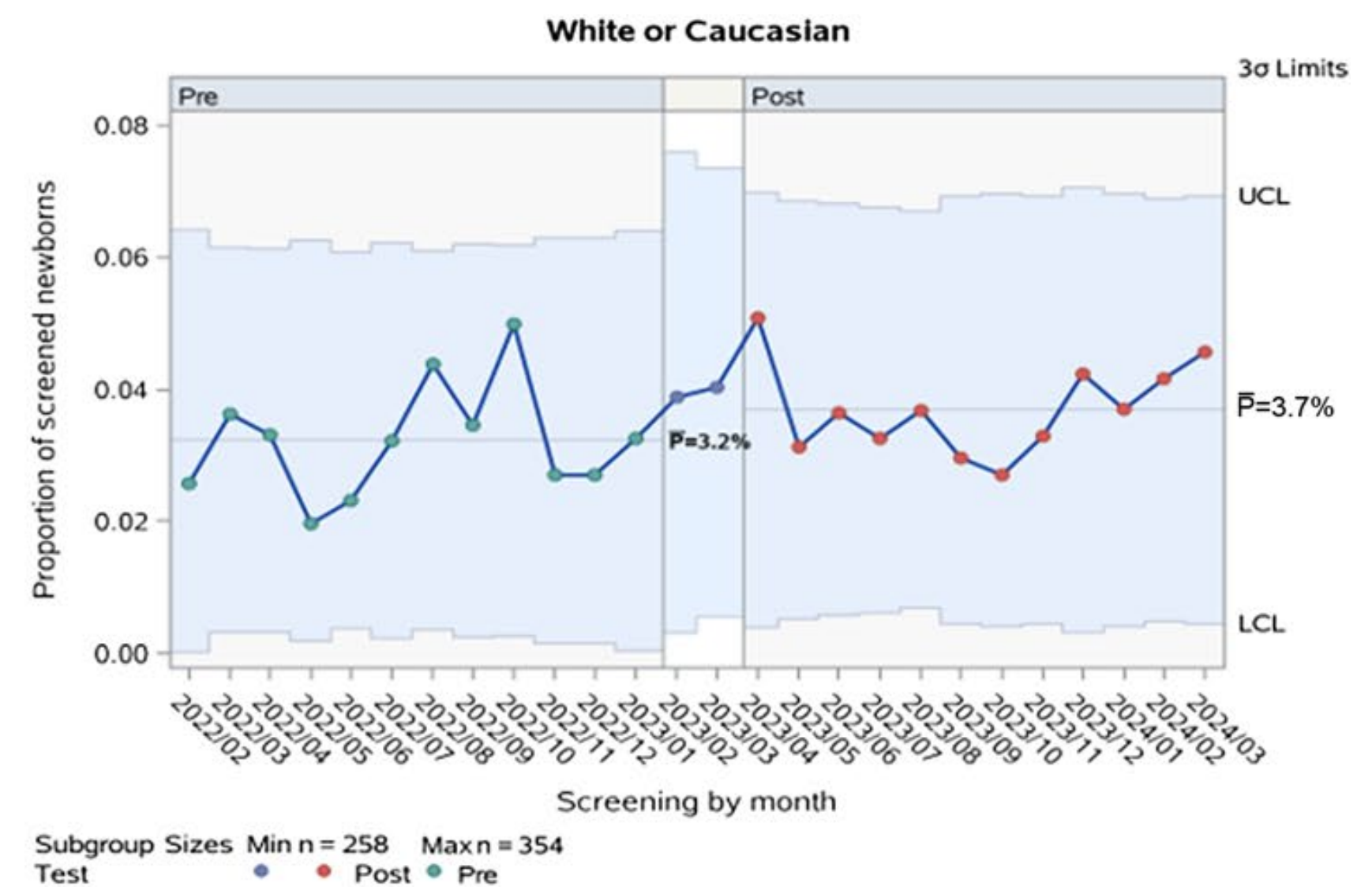
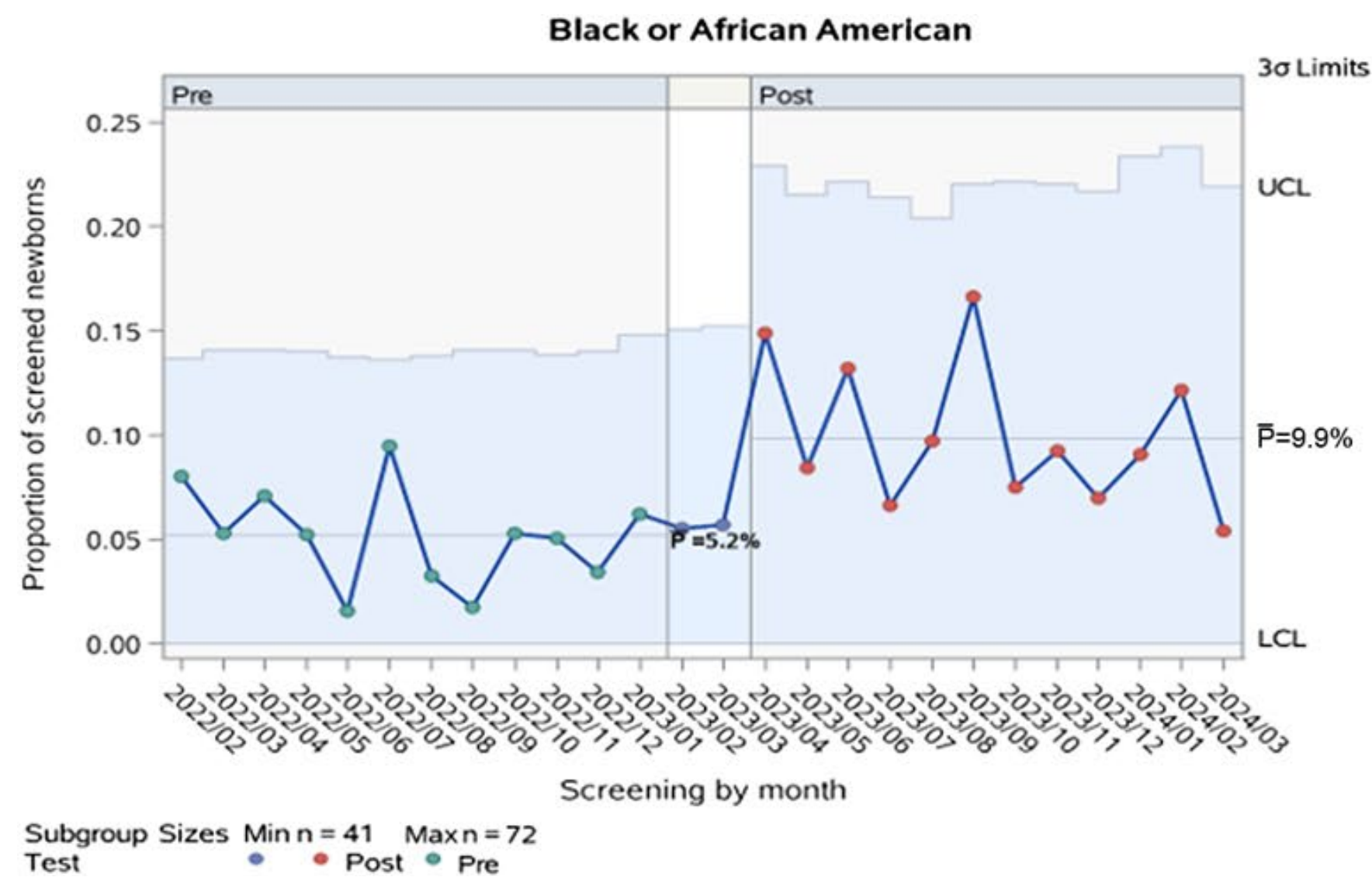
## Assessing the clinical utility of toxicology testing in the peripartum period

Molly R. Siegel, MD; Samuel J. Cohen, MD; Kathleen Koenigs, MD; Gregory T. Woods, MD; Leah N. Schwartz, BA; Leela Sarathy, MD; Joseph H. Chou, MD, PhD; Mishka Terplan, MD, MPH; Timothy Wilens, MD; Jeffrey L. Ecker, MD; Sarah N. Bernstein, MD; Davida M. Schiff, MD

Clinical Rationale for Test	Unexpected Positive Results, n (%)
<b>High Yield Indications</b>	
History of Recent SUD (within past 2 yrs) (N=422)	45 (10.7%)
Inadequate Prenatal Care (N=154)	9 (5.8%)
Maternal MOUD w/o active SUD in past 2 yrs (N=159)	6 (3.8%)
<b>Medium Yield Indications</b>	
Maternal Medical Indications (N=351)	8 (2.3%)
History of SUD, in remission >2yrs (N = 159)	1 (1.7%)
Maternal Cannabis Use (N=699)	11 (1.6%)
<b>Low Yield Indications</b>	
Monitoring for Controlled Substance Rx (N=37)	0 (0%)
Infant Clinical Presentation (N=69)	0 (0%)
Other/Unknown (N=83)	0 (0%)
<b>TOTAL (N=2036)</b>	<b>80 (3.9%)</b>

# Criteria/Risk-based testing


- Overlap with other SDOH
- Can exacerbate disparity



# Clinical indications

FROM THE AMERICAN ACADEMY OF PEDIATRICS | CLINICAL REPORT | NOVEMBER 01 2020

## Neonatal Opioid Withdrawal Syndrome

Stephen W. Patrick, MD, MPH, MS, FAAP ; Wanda D. Barfield, MD, MPH, FAAP; Brenda B. Poindexter, MD, MS, FAAP;  
COMMITTEE ON FETUS AND NEWBORN, COMMITTEE ON SUBSTANCE USE AND PREVENTION; James Cummings, MD, FAAP;  
Ivan Hand, MD, FAAP; Ira Adams-Chapman, MD, MD, FAAP; Susan W. Aucott, MD, FAAP; Karen M. Puopolo, MD, FAAP;  
Jay P. Goldsmith, MD, FAAP; David Kaufman, MD, FAAP; Camilia Martin, MD, FAAP; Meredith Mowitz, MD, FAAP;  
Lucien Gonzalez, MD, MS, FAAP; Deepa R. Camenga, MD, MHS, FAAP; Joanna Quigley, MD, FAAP; Sheryl A. Ryan, MD, FAAP;  
Leslie Walker-Harding, MD, FAAP

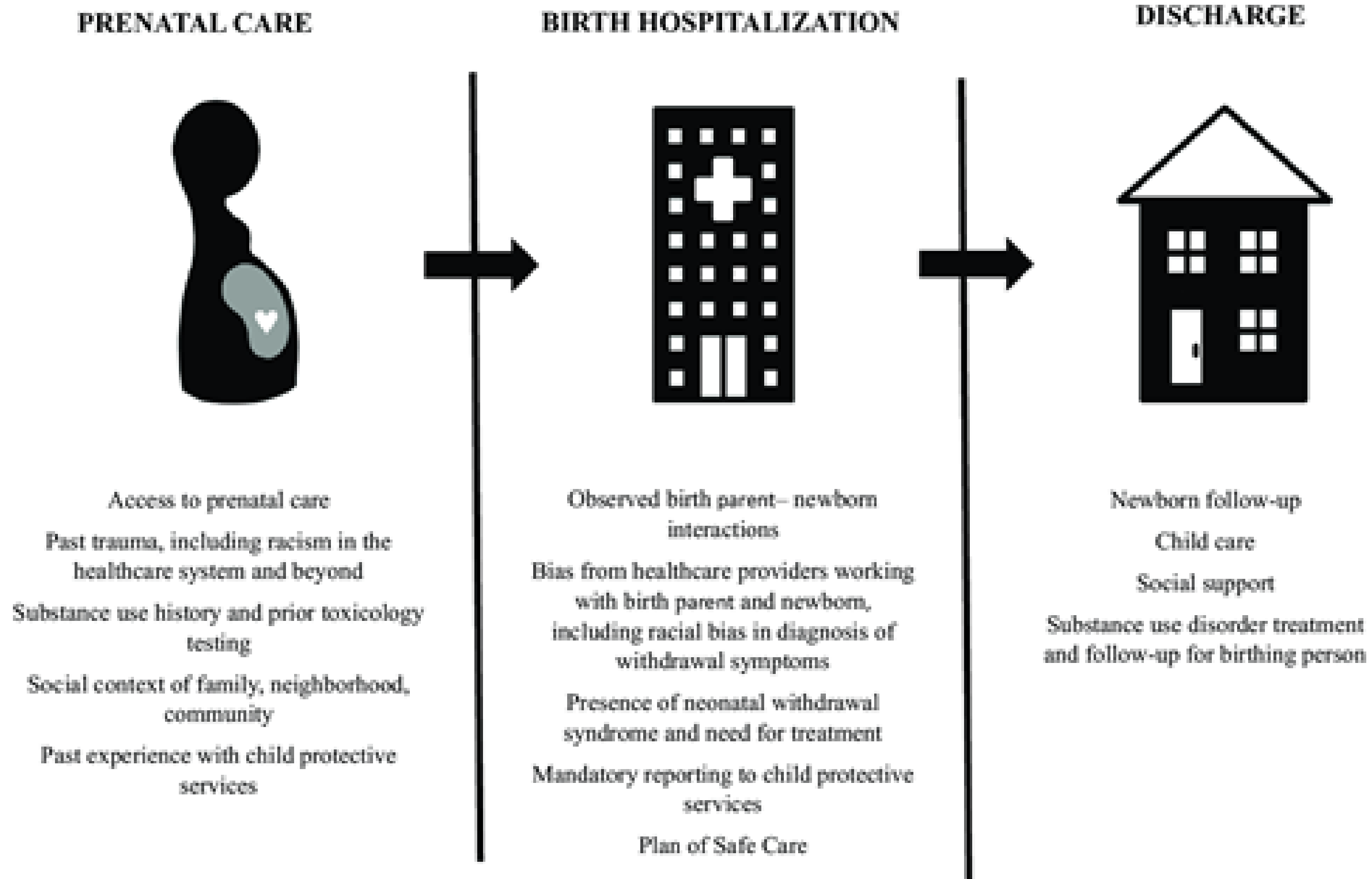
- AAP clinical report 2020: “when it will inform clinical management”
  - = symptoms of intoxication or withdrawal in parent or newborn
    - or if requested by parent?
- Still requires conversation with parent of potential benefits/harms

# Can NTT predict safety?

- Breastfeeding?
- Safety in the home?



# Part of a care continuum



\*Care for the newborn-parent dyad is part of a continuum that begins during fetal life and extends beyond the birth hospitalization.

# Informed Consent

- *nonmaleficence, autonomy, and the confidentiality (vs. paternalism, autonomy of newborn)*
- **Components:**
  - Explicit clarification for the provider and patient about the goal of testing
  - Discussion of who will have access to the results
  - Review of ramifications of a positive test
  - Describe the right for a person to refuse testing, and the limits on refusal (for minors)
- **Written consent preferred**



Slide adapted from D Schiff

ACOG Committee Opinion No. 711, 2017; ASAM, 2023; SAMHSA; Ecker et al. AJOG 2019; Charlestown v. City of Ferguson, 2001

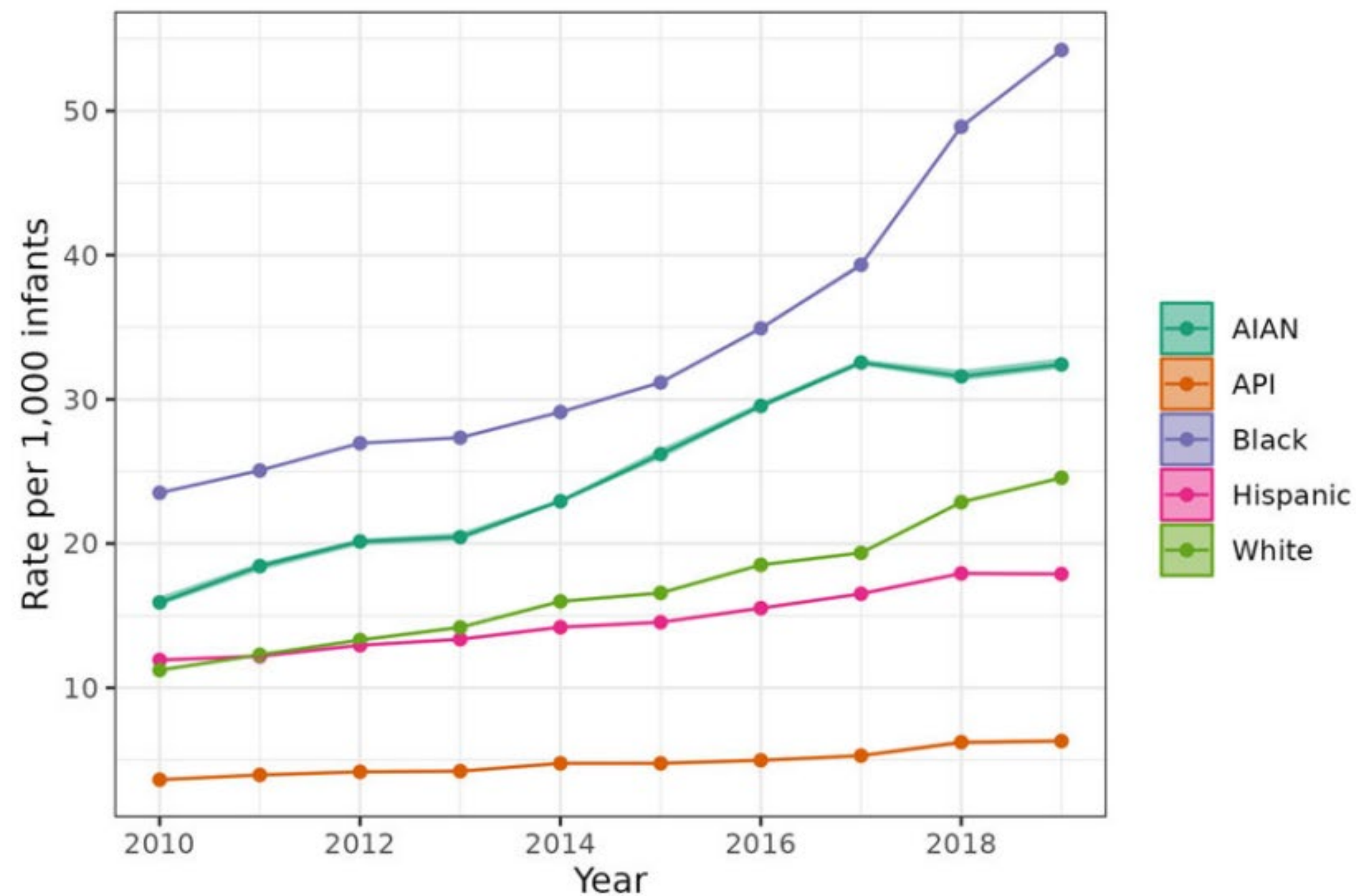
# Responding to test results

- Confirmatory/definitive testing
- Disclosure of results
- Provision of resources
- Reporting...



# Reporting

- In 2019, >5% of Black infants in the US were subjected to child welfare investigation from medical professional report



**FIG. 2.** U.S. child welfare investigations of infants (age < 1 year) initiated following a medical professional report, 2010–2019 by child race/ethnicity. *Intervals* indicate uncertainty from missing race/ethnicity data.

# Policy and Legislation

# Hospital Policy



- Development
  - Include all stakeholders including patient/families
- Universal *screening*
- Criteria for NTT
- Informed consent
- Recommendations for CPS referrals and other interventions
  - Consideration of local and federal requirements
  - Knowledge of local resources
- Health equity
  - Trauma informed, person-first
  - Supportive over punitive consequences
  - Ongoing assessment of health equity

# Legislative Policy

- Need for NTT as part of reporting varies
- CARA (Comprehensive Addiction and Recovery Act of 2016)
  - Amendment to CAPTA
  - Need to identify, follow dyads; ensure appropriate supports in place
    - Ensure the safety and well-being of infants following their release from the care of health-care providers by **(1) addressing the health and substance use disorder treatment needs of the infant and affected family member or caregiver and (2) monitoring these plans to determine whether and how local entities are making referrals and delivering appropriate services to the infant and affected family member or caregiver (in accordance with State requirements)**
    - Develop plans of safe care for infants affected by all substance use (not just illegal substance use, as was the requirement prior to this change)
  - Need to report to state
    - But what does this mean?
    - Advocacy for dual-reporting systems



# Conclusions

# Next steps/lingering questions

- Balancing measures
  - What are consequences of reduced NTT/reporting to CPS?
- Evidenced-based tools for screening in neonatal population
- Guidance from major medical organizations to standardize best practice approaches to toxicology testing
- Partnerships between medical systems and legal and social systems

# Conclusions

- NTT is frequently used, but has many limitations and potential harms
- A clinically-based approach is preferred to avoid unintended harms and inequity, and aligns with the ethical principles of beneficence, nonmaleficence, and justice
- NTT cannot replace patients' voices, our clinical judgement, or the need for care coordination and support across the continuum to support families with SUD
- Ongoing advocacy at all levels is needed to further promote ethical, equitable approaches to NTT

# Ethically-Informed Best Practices for NTT

## Five Crucial Considerations

1. Known or suspected prenatal substance exposure
2. Indication(s) for, method, and potential utility of newborn toxicology testing
3. Obtaining informed consent for testing
4. Timing of, response to, and communication of testing results
5. Indication for Child Protective Services referral

## Five Ethical Questions

1. What additional information will neonatal toxicology testing provide? Apply the principles of *beneficence and nonmaleficence*.
2. Does the decision to obtain neonatal toxicology testing uphold the principle of *justice*?
3. Has the healthcare team afforded the birthing person the opportunity to make an informed decision about neonatal toxicology testing based upon the principle of *autonomy*, and *trauma-informed care ethics* and *feminist ethics* frameworks?
4. How will the framework of *confidentiality* factor into the communication of testing results?
5. How will test results impact the family and discharge planning, including the decision for CPS referral? Consider *ethics of care and narrative ethics* frameworks for the family.

# Questions or Comments?

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